UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,495	08/25/2003	Bertram N. Ezenwa	282.037	2371

7590 12/23/2005

William T. Kryger
BOYLE, FREDRICKSON, NEWHOLM, STEIN & GRATZ S.C.
Suite 1030
250 E. Wisconsin Avenue
Milwaukee, WI 53202

EXAMINER	
APANIUS, MICHAEL	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,495	EZENWA, BERTRAM N.	
	Examiner	Art Unit	
	Michael Apanius	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25,29 and 30* is/are rejected.

7)☒ Claim(s) *26-28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 August 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because the reference numerals are "hand-drawn" and one of the wires connected to controller "55" in figure 3 is not sufficiently dark and well-defined.

2. Furthermore, "10" is not labeled in figure 1 as is recited at page 4, line 6 of the specification.

3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:

a. At page 3, last line, "and" should be deleted.

b. At page 4, line 2, --and-- should be added after "the present invention;".

c. At page 5, line 30 - page 6, line 1, "one or modules" is unclear.

d. All recitations of "hand 62" in the specification should be --hand 67-- to be consistent with the drawings.

e. At page 7, line 13, "disc 84" should be --disc 86--.

f. At page 7, line 24, "vertical adjustment 87" should be -- vertical adjustment 82--.

g. At page 8, line 12, "load cell 80" should be --load cell 100--.

h. At page 8, line 19, "excitation" should be --sensing--.

i. At page 10, line 5, "if the research option" should be the beginning of a new sentence.

Appropriate correction is required.

Claim Objections

5. Claim 8, 14 and 16 are objected to because of the following informalities:

a. At claim 8, line 2, "conduction" should be deleted to be consistent with the earlier recited claim language.

b. At claim 14, line 1, "a pressure mounting structure" should be --the pressure mounting structure--.

c. At claim 16, line 2, a word(s) is missing between "electrode" and "against".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 13 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear how the light source (50) can project a grid on the hand of the patient when the sensing electrode (25) is disposed between the light source and the hand and would block the projection of light from the light source (see figure 2). If the light source projects from its perimeter, it is also not clear how it can project an accurate grid on the hand. Therefore, the claimed subject matter fails to comply with the enablement requirement because the disclosure fails to enable one skilled in the art to properly construct the light source to project a grid onto a hand.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. At claim 14, line 2, "the pressure sensor" lacks antecedent basis. Note that claim 1 does not recite "a pressure sensor".

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemmen (US 5,327,902).

13. In regards to claim 1, Lemmen discloses an apparatus for sensing the amplitude of a signal traveling through a body that is generated by an excitation device, comprising: a sensing electrode (10) operatively engagable with the body under a pressure downstream of the excitation device for sensing a signal generated by an excitation device; and a pressure mounting structure (30) operatively connected to the sensing electrode for controlling the pressure at which the sensing electrode engages the body. Note that changing the force with which the pressure mounting structure is held against the skin controls the pressure.

14. In regards to claim 10, the apparatus has a positioning structure (50) operatively connected to the sensing electrode for positioning the sensing electrode at a user selected location adjacent the body.

15. In regards to claim 11, the positioning structure is a vertical positioning device which allows a user to adjust the vertical position of the sensing electrode relative to the body when the arm is held straight up.

16. Claims 25, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemmen (US 5,327,902).

17. In regards to claim 25, Lemmen discloses a method for sensing a signal traveling through a body, the signal generated by an excitation device operatively engaging the body, the method comprising the steps of: positioning a sensing electrode on the body (column 5, lines 30-33); exerting a pressure on the sensing electrode against the body (column 5, lines 30-33); and receiving the signal with the sensing electrode (column 5, lines 37-39).

18. In regards to claim 29, the amplitude level of the signal is measured (column 5, lines 37-42).

19. In regards to claim 30, the above steps are repeated (column 5, lines 39-42).

20. Claims 1-3, 10, 11, 15, 16, 20 rejected under 35 U.S.C. 102(b) as being anticipated by Narishige et al. (US 4,526,169).

21. In regards to claims 1, 15 and 20, Narishige et al. disclose an apparatus that is capable of sensing the amplitude of a signal generated by an excitation device operatively engaging the body, comprising: a sensing electrode (P) operatively engagable with the body under a pressure that is capable of being placed downstream from an excitation device to sense a signal generated by an excitation device; and a pressure mounting structure (figure 1) operatively connected to the sensing electrode for controlling the pressure at which the sensing electrode engages the body.

22. In regards to claims 2 and 15, the pressure mounting structure includes a pressure source (figure 2) operatively connected to the sensing electrode for applying the pressure at which the sensing electrode engages the body.

23. In regards to claims 3 and 16, the pressure source includes a micrometer (MH) configured to adjust the pressure at which the sensing electrode engages the body. Note that changing the position of the electrode by pressing it against the body will adjust the pressure at which the electrode engages the body.

24. In regards to claim 10, the apparatus has a positioning structure (26) operatively connected to the sensing electrode for positioning the sensing electrode at a user selected location adjacent the body.

25. In regards to claim 11, the positioning structure has a vertical positioning device (26z) which allows a user to adjust the vertical position of the sensing electrode relative to the body when the arm is held straight up.

26. Claims 1, 2, 4-6, 15, 17, 18, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho (US 6,174,290).

27. In regards to claims 1, 15 and 20, Cho discloses an apparatus that is capable of sensing the amplitude of a signal generated by an excitation device operatively engaging the body, comprising: a sensing electrode (3) operatively engagable with the body under a pressure that is capable of being placed downstream from an excitation device to sense a signal generated by an excitation device; and a pressure mounting structure (1) operatively connected to the sensing electrode for controlling the pressure at which the sensing electrode engages the body.

28. In regards to claims 2 and 15, the pressure mounting structure includes a pressure source (4) operatively connected to the sensing electrode for applying the pressure at which the sensing electrode engages the body.

29. In regards to claims 4 and 17, the apparatus further comprises a pressure sensor (5) disposed adjacent the sensing electrode.

30. In regards to claims 5 and 18, the pressure sensor is a load cell (column 5, line 18).

31. In regards to claims 6 and 23, the apparatus further comprises a controller (figure 3) electrically connected to the pressure sensor for receiving the pressure signal and to the sensing electrode for receiving the signal sensed by the sensing electrode.

32. Claims 1, 2, 10, 12, 15 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Walters (US 3,067,749).

33. In regards to claims 1, 15 and 20, Walters discloses an apparatus that is capable of sensing the amplitude of a signal traveling through a body that is generated by an excitation device, comprising: a sensing electrode (20) operatively engagable with the body under a pressure that is capable of being placed downstream from an excitation device to sense a signal generated by an excitation device; and a pressure mounting structure (30) operatively connected to the sensing electrode for controlling the pressure at which the sensing electrode engages the body.

34. In regards to claims 2 and 15, the pressure mounting structure includes a pressure source (50) operatively connected to the sensing electrode for applying the pressure at which the sensing electrode engages the body.

35. In regards to claim 10, the apparatus has a positioning structure (40, 42, 44) operatively connected to the sensing electrode for positioning the sensing electrode at a user selected location adjacent the body.

36. In regards to claim 12, the positioning structure is a dial configured to rotate the sensing electrode about a horizontal axis so as to allow a user to control an angle at which the sensing electrode engages the body.

Claim Rejections - 35 USC § 103

37. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

38. Claims 2, 4-9, 15, 17, 18, 20, 23 and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Lemmen (US 5,327,902) in view of Cho (US 6,174,290). Lemmen discloses a sensing electrode (10), a pressure mounting structure (30), and a controller (120). However, Lemmen does not expressly disclose a pressure source or a pressure sensor. Cho teaches a pressure source (4) and a load cell (5) for the purpose of ensuring that the electrode contacts the body with the proper force necessary for obtaining precise data (column 1, lines 43-50). The controller of Lemmen when modified by Cho is capable of being programmed (column 4, lines 32-33) to determine a pressure normalization ration, to normalize the sensed signal, and to display a pressure value. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a pressure source and load cell in the apparatus of Lemmen as taught be Cho in order to ensure that the electrode contacts the body with the proper force necessary for obtaining precise data.

39. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemmen (US 5,327,902) in view of Heilbrun et al. (US 5,389,101). Lemmen discloses the limitations of claim 10 as noted above in regards to claims 1, 10 and 11. However, Lemmen does not expressly disclose a light source. Heilbrun et al. teach a light source (column 10, lines 7-11) configured to illuminate a grid on the body for the purpose of creating a workspace coordinate framework for defining the location of a medical instrument relative to a body region (column 3, lines 6-10). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used

a light source in the apparatus of Lemmen as taught by Heilbrun et al. in order to create a workspace coordinate framework.

40. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemmen (US 5,327,902) as modified by Cho (US 6,174,290) as applied to claims 2, 4-9, 15, 17, 18, 20, 23 and 24 above, and further in view of Heilbrun et al. (US 5,389,101). Lemmen as modified by Cho discloses the limitations of claim 15 as noted above in regards to claims 2, 4-9, 15, 17, 18, 20, 23 and 24. However, Lemmen as modified by Cho does not expressly disclose a light source. Heilbrun et al. teach a light source (column 10, lines 7-11) configured to illuminate a grid on the body for the purpose of creating a workspace coordinate framework for defining the location of a medical instrument relative to a body region (column 3, lines 6-10). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a light source in the apparatus of Lemmen combined with Cho as taught by Heilbrun et al. in order to create a workspace coordinate framework.

41. Claims 1-4, 14-17 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US 5,485,848) in view of Inukai et al. (US 5,865,761). In regards to claims 1, 15 and 20, Jackson et al. disclose an apparatus comprising: a pressure mounting structure (figure 4, 86) for controlling the pressure at which the apparatus engages the body. In regards to claims 2 and 15, the pressure mounting structure includes a pressure source (102; paragraph bridging column 6 and column 7).

In regards to claims 3, 16 and 22, the pressure source is a micrometer configured to adjust the pressure at which the apparatus engages the body. In regards to claims 4, 14 and 17, the apparatus further comprises a pressure sensor (110). In regards to claims 14 and 21, the pressure mounting structure is a strap operatively connected to the pressure sensor. Jackson et al. do not expressly disclose a sensing electrode. Inukai et al. teach a sensing electrode (90) combined with a strap-like blood pressure measuring device for the purpose of allowing multiple simultaneous measurements to be made in a single set-up (column 1, lines 56-62). The sensing electrode of Inukai et al. is capable of sensing a signal traveling through the body that was generated by an excitation device. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have added a sensing electrode to the apparatus of Jackson et al. as taught by Inukai et al. in order to make multiple simultaneous measurements in a single set-up.

Allowable Subject Matter

42. Claims 26-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

43. The following is a statement of reasons for the indication of allowable subject matter: no prior art of record teaches or fairly suggests a method for sensing a signal traveling through a body comprising the step of determining a pressure normalization ratio in response to a pressure signal as set forth in claim 26.

Conclusion

44. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,711,248 discloses a physiological pressure monitor. US 5,215,100 discloses a nerve conduction monitoring system and electrode supporting structure. US 5,333,618 discloses a portable self-contained instrument for the measurement of nerve resistance of a patient. US 5,540,235 discloses an adapter for neurophysiological monitoring with a personal computer. US 5,851,191 discloses an apparatus and method for assessment of neuromuscular function.

45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

46. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

47. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA

CHARLES MARMOR
PRIMARY EXAMINER